REMARKS

STATUS OF THE CLAIMS.

Claims 1-35 and 37-55 are currently pending in the application with entry of the present amendment. Of such claims, 1-34, 38, 45-48, and 53-55 are withdrawn from current consideration. Claim 36 is cancelled herein and its limitations incorporated into claim 35. Claim 35 is amended herein to more clearly describe embodiments of the invention. These changes introduce no new matter and support is present in the application as originally filed (e.g., paragraphs 21 and 22, etc.). The changes are made without prejudice and are not to be construed as abandonment of any previously claimed subject matter or agreement with any objection or rejection of record. Accordingly, entry of the Amendment is respectfully requested.

OBJECTION TO CLAIMS

Claim 36 was objected to in the Office Action as having improper dependent form. More specifically, the Examiner helpfully pointed out that claim 36 recited "a polysulfonated compound" while its antecedent claim (claim 35) already recited examples of such compounds. Applicants amend claim 35 herein to recite the limitations of claim 36 and cancel claim 36. Because no new matter is added by such change, Applicants respectfully request entry of the change and withdrawal of the objection.

35 U.S.C. §112 FIRST PARAGRAPH.

Claims 37, 39, 42, 43-44, 49, and 51 were rejected in the Office Action under 35 U.S.C. §112, first paragraph as allegedly lacking enablement for sulfonated compounds other than LSA. The Office Action alleges that the specification does not provide enablement for "any sulfonated compounds isolated from a natural source or any derivatives of a lignin in claims 49 and 51, and any compounds having spermicide function (i.e., in claims 39 and 43)." Applicants respectfully traverse.

The Office Action alleges that undue experimentation would be needed for a skilled artisan to fully practice the current invention because sulfonated compounds isolated from a natural source, sulfonated compounds derived from lignin, and compounds having spermicidal action could be selected from a number of choices. The Action cites to *In re Wands*, 8 USPQ2d 1400, for guidance in determining whether a disclosure requires undue experimentation and is, thus, not enabled. The factors as listed in the Action, include: the nature of the invention, the state of the prior

art, the relative skill of those in the art, the predictability or unpredictability of the art, the breadth of the claims, the amount of direction or guidance presented, the presence or absence of working examples, and the quantity of experimentation necessary. *See* also, M.P.E.P. §2164.01(a).

The Office Action focuses its allegations on the amount of direction or guidance presented, the predictability or unpredictability of the art, and the presence/absence of working examples and the quantity of experimentation necessary.

In discussing the amount of direction/guidance presented by the specification, the Office Action performs an analysis for a written description standard. However, in determining enablement, Applicants respectfully point out that the amount of direction/guidance presented by a disclosure is but one of numerous factors to weigh in determination. Additionally, no matter which standard is applied, the specification presents ample guidance and direction for those of skill in the art to perform the invention. For example, in terms of determining sulfonated compounds of the invention, the specification presents guidance such as, e.g., Examples 1-3 and Figure 7, etc., which set out experimental details to help in delineation of possible compounds. The Examples in the specification give guidance in testing a compound's effect on, e.g., a sperm's ability to bind to the zona pellucida (Example 1), a compound's ability to prevent *in vitro* fertilization (Example 2), and labeling of sperm with compounds (Example 3). Furthermore, the specification is replete with references giving guidance, e.g., by example, to those of skill in the art, in testing compounds and their ability to prevent fertilization, act as contraceptives, etc. In regard to the term "spermicide," applicants note that it is a term recognized by those of skill in the art. Those of skill would know, or have available, various different spermicides. Additionally, spermicides are not new or unknown biological materials that ordinary skilled artisans would easily miscomprehend. Thus, it is adequately described and enabled by the specification. *See Amgen v. Hoechst*, 314 F.3d 1313 (Fed. Cir. 2003).

The Action also alleges that the specification is not enabling due to the unpredictability of art in the field and that one of skill in art would not be able to fully identify the compounds claimed since "not any [sic] derivatives of lignin are bioactive or hav[e] pharmaceutical activities." Again, applicants respectfully point out that the specification is replete with guidance on how to determine compounds with bioactivity. The Examples section of the application details procedures, e.g., which aid those of skill in the art to determine the members of compounds

involved. Additionally, numerous references within the specification also present and detail similar protocols. Procedures and protocols for determining therapeutic/prophylactic effects, side effects, etc. are well known to those of skill in the art. As explained in more detail below, the standard for enablement is whether undue experimentation is needed to make and use the invention, not whether any experimentation at all is needed.

Finally, the Office Action also alleges that the specification only provides two particular compounds to be tested and, thus, fails to provide support for other compounds and would require those of skill to "perform an exhaustive search for the embodiments." Again, however, Applicants assert that the specification and the references therein, provide ample guidance to make or use the invention.

In evaluating enablement, the test is "whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *See* M.P.E.P. §2164.01. If there is considerable direction and guidance in the specification, especially when the level of skill in the art is high as the Office Action admits at page 4, then a disclosure can be enabling. *See* M.P.E.P. §2164.01(a). Additionally, as stated in *In re Colianni*, 561 F.2d 220, an "extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." "'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *See In re Wands*, 858 F.2d 731, 737, citing *In re Angstadt*, 537 F.2d 489.

The specification as filed, as stated previously, contains ample guidance and direction for those skilled in the art. For example, paragraphs 64 *et seq.* list numerous references for describing/determining bioactivity of sulfonated compounds. Paragraphs 72 *et seq.* give references for methods of producing lignin derivatives and bioactivity of such. Also, the Examples of the specification detail procedures for, e.g., determining a compound's effect on sperm's ability to bind to the zona pellucida, testing for prevention of *in vitro* fertilization, and labeling of sperm with compounds (e.g., to determine localization), etc.

In summary, the application provides extensive guidance for those skilled in the art to make and use the invention. No undue experimentation is needed to do so. Any experimentation

required is merely routine in nature and is amply guided by the information in the specification, the references listed therein, and the general knowledge of those skilled in the art. Thus, because the specification provides enablement for the claims, Applicants respectfully request withdrawal of the rejection.

35 U.S.C. §112 SECOND PARAGRAPH.

Claims 35, 37, 49, and 51-52 were rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite by failing to particularly point out and distinctly claim the subject matter regarded by applicants as the invention. More specifically, the Office Action alleges that the phrases "derivatives thereof" in claims 35 and 37 and "a derivative thereof" in claim 49 (and hence its dependents 51 and 52 as well) render such claims indefinite. The Action states that one of ordinary skill could not interpret the metes and bounds of such phrases because one of ordinary skill in the art would "clearly recognize so many various possible derivatives." Applicants respectfully traverse.

The application presents numerous guides in determining "derivatives" present in the claims. For example, paragraph 59 lists types of derivatives of the compounds involved as well as exemplary possibilities of derivatives of the compounds involved:

> In some embodiments, the compound of the present invention comprises a polysulfonated compound. Various derivatives, e.g., salt forms, e.g., glycosylated forms, e.g., (poly)saccharide forms and the like, of the above compounds are also included in the present invention. Salts derivatives of the compounds can include, e.g., calcium, e.g., sodium, e.g., ammonium, e.g., chromium, e.g., magnesium, and the like. For example, salts derivatives of compounds include but are not limited to, e.g., lignosulfonic acid, sodium salt, lignosulfonic acid, calcium salt, poly(vinylsulfonic acid, sodium salt) and the like. Polymers of the above compounds are also included in the present invention. The polymers can comprise homologous monomer units or heterologous monomer units.

Specification at paragraph 59. Thus, those of skill in the art would be able to determine/produce "derivatives" as recited in claims 35 and 37.

Additionally, guidance for determination/production of derivatives of lignin are also replete throughout the specification which would allow one of ordinary skill in the art to understand the metes and bounds of the claims. For example, paragraph 60 gives a number of references for determination/production of compounds (e.g., derivatives) from lignin, etc. Also, paragraphs 71

through 76 give further guidance concerning lignin derivatives. Again, numerous references are presented (as well as exemplary derivatives) which allow those of skill in the art to determine the scope of derivatives in the present claims. For example, paragraph 73 presents LSA, sulfonated kraft lignin (or alkali lignin) as derivatives of lignin. Thus, Applicants respectfully request withdrawal of the rejection.

35 U.S.C. §102(b).

Pillai

Claims 35-36, 39-42, and 49-50 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Pillai et al. (1997 *Aquatic Toxicology*, 37:139-156). Applicants respectfully traverse.

The Office Action alleges that Pillai discloses compositions having lignin-derived macromolecules "containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, and a sperm in an aqueous solution (a pharmaceutical excipient) in varying concentrations, wherein LDM may inhibit the sperm acrosome reaction." Office Action at page 9.

In order for a reference to anticipate a claim "the reference must teach every element of the claim." M.P.E.P. §2131. Applicants respectfully submit that Pillai does not teach every element of the claims. For example, notwithstanding the allegations of the Office Action, Pillai does not teach compositions comprising a pharmaceutically acceptable excipient as recited in each of the instant independent claims, from which the other claims in question depend.

Examination of the passages of Pillai cited by the Office Action (especially the passages in Pillai § 2.5) reveals that Pillai used compositions of sperm ("dry," *see* Pillai §2.1) and LDM (or LDM eluted from an SDS-PAGE gel, *see* Pillai §2.4) for preparation of an *in vitro* assay. The sperm and LDM were mixed with a jelly solution isolated from sea urchin eggs. This, in turn, was fixed for spectroscopic analysis with seawater buffered with glutaraldehyde or paraformaldehyde in preparation for visualization and scoring. *See* Pillai at page 140.

Again, such combinations are lacking the recited components of the current compositions. For example, the compositions in Pillai do not include a pharmaceutically acceptable excipient. The Office Action states that the "aqueous solution" in Pillai is a pharmaceutically acceptable excipient. However, Applicants submit that the materials used to fix the sperm in Pillai, seawater buffered with glutaraldehyde or paraformaldehyde, are not pharmaceutically acceptable excipients. The Pillai constituents are for an *in vitro* assay, not for pharmaceutical use. Both

glutaraldehyde and paraformaldehyde are chemicals used for fixing cells for assay. They are thought to act by forming hydroxy-methylene bridges between reactive end-groups of adjacent protein chains. Both glutaraldehyde and paraformaldehyde pose acute and chronic health hazards (e.g., severe irritation, destruction to mucous membrane and respiratory tract tissues, corrosive burns, etc.). In marked contrast to Pillai, the compositions of the current claims recite the presence of a pharmaceutically acceptable excipient (i.e., one capable of use pharmaceutically, e.g., as a drug or for a medical/health purpose) instead of the presence of glutaradehyde/paraformaldehyde which would pose health hazards used in a pharmaceutical/medical context.

In summary, as opposed to Pillai, the current claims require the presence of a pharmaceutically acceptable excipient. Pillai contains the chemicals glutaraldehyde/paraformaldehyde in its compositions. Thus, Pillai does not teach every element of the claims. Applicants therefore respectfully request that the rejection be withdrawn.

Anderson

Claims 35-36 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Anderson et al. (2000, *J. of Andrology*, 21(6):862-875). Applicants respectfully traverse.

As stated previously, in order for a reference to anticipate a claim "the reference must teach every element of the claim." M.P.E.P. §2131. The Office Action alleges that Anderson discloses compositions having a particular polyvinylsulfonic acid derivative, namely poly(styrene-4-sulfonate) or N-PSS, along with sperm in an aqueous solution which the Action terms a pharmaceutical excipient.

Applicants respectfully submit that Anderson does not teach every element of claims 35-36 as amended. More explicitly, Anderson does not teach a composition as described in the present application that does not comprise a polystyrene sulfonated compound as recited in amended claim 35.

In order to expedite prosecution and to more clearly differentiate the current invention from Anderson, Applicants herein amend claim 35 to explicitly recite the absence of a polystyrene sulfonate in the composition. Support for such limitation can be found in the specification as originally filed, e.g., paragraphs 21 and 22. For example, paragraph 22 states that the methods of the invention comprise use of compositions having sulfonated compounds other than, *inter alia*,

polystyrene sulfonate. Paragraph 22, in describing compositions of the invention, specifically recites that the compositions include those noted in the description of the methods of the invention (i.e., compositions as described in paragraph 21 such as those not comprising polystyrene sulfonate).

Modification of the language in claim 35, thus, does not comprise new matter since the information is present in the specification as originally filed. As stated by the M.P.E.P. at §2163.06, "information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter." Because the amended claim presents no new matter, its entry is respectfully requested.

A comparison of amended claim 35 and Anderson shows that Anderson does not teach every element of the current claim. For example, Anderson teaches compositions having a polystyrene sulfonate. As opposed to Anderson, the current claim explicitly does not comprise a polystyrene sulfonate compound. Thus, Anderson does not teach every element of the amended claim 35. Claim 36 is cancelled herein, *see* above, thus obviating any rejection to it. Applicants therefore respectfully request that the rejection to claims 35 and 36 be withdrawn.

35 U.S.C. §103(a).

Pillai and Anderson

Claims 37, 43-44, and 51-52 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Pillai et al. (1997 *Aquatic Toxicology*, 37:139-156) and Anderson et al. (USPN 6,063,773). Applicants respectfully traverse.

In brief, Applicants submit that the Office Action has not established a *prima facie* case of obviousness because the record fails to provide the elements necessary for a *prima facie* case.

For a *prima facie* case of obviousness, three requirements must be met. First, the prior art reference(s) cited must teach all of the limitations of the claims. Second, a motivation must exist to modify the reference(s) or to combine the teachings to produce the claimed invention. Third, there must be a reasonable expectation of success. M.P.E.P. §2143. Furthermore, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based upon the disclosure of the Applicants. M.P.E.P. §2142.

The Office Action alleges that a *prima facie* case of obviousness arises because "both a lignosulfonate or a lignosulfonic acid, and the known spermicide, nonoxynol-9 are known to be useful in a composition for contraception or inhibiting fertilization." The Action cites *In re Kerkhoven*, 205 USPQ 1069 by stating that it is "*prima facie* obvious to combine two active composition components into a single composition to form a third composition useful for the very same purpose." *Kerkhoven* based its rejections upon combination of two conventional spray-dried detergents. *See* also M.P.E.P. §2144.06.

Notwithstanding the allegations of the Office Action, however, those of skill in the art would not have been motivated to combine lignosulfonate or a lignosulfonic acid with a spermicide such as nonoxynol-9 (i.e., to combine Pillai and Anderson). Nonoxyol-9 and lignosulfonate and lignosulfonic acid are not components for "the very same purpose." More specifically, nonoxynol-9 is a spermicide while lignosulfonate and lignosulfonic acid inhibit acrosome reaction of sperm. Thus, no motivation to combine the references (i.e., Pillai and Anderson) would *prima facie* exist and, thus, the Office Action has not presented a *prima facie* case of obviousness. Applicants, therefore, respectfully request that the rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. In the event that substantive matters are felt to remain, Applicants formally request a telephone conference prior to preparation of a further Office Action. In such case, the Examiner is invited to telephone the undersigned at (510) 769-3507.

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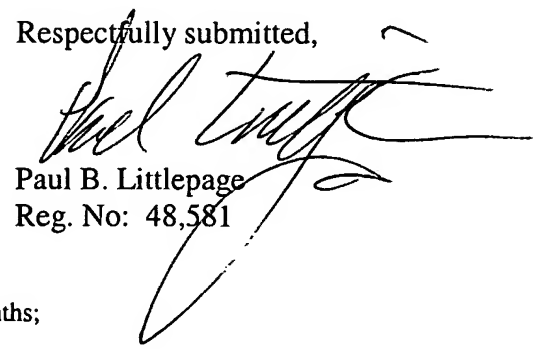
Respectfully submitted,



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ATTACHMENTS:

1) A petition to extend the period of response for 3 months;
3) A Transmittal; and,
4) A Receipt Indication Postcard.